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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09.487.979      | 01/20/2000  | Boris Skurkovich     | 0011-1U9            | 3797             |

28977 7590 06/02/2003

MORGAN, LEWIS & BOCKIUS LLP  
1701 MARKET STREET  
PHILADELPHIA, PA 19103-2921

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| EXAMINER |
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DECLoux, AMY M

|          |              |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1644

DATE MAILED: 06/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/487,979

Applicant(s)

SKURKOVICH ET AL.

Examiner

Amy M. DeCloux

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2003 and 11 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 42, 45, 46 and 48-50 is/are pending in the application.
- 4a) Of the above claim(s) 45 and 48-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42 and 46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18 and 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12-11-02 has been entered.

Claims 42, 45-46 and 48-50 are pending.

Claims 45 and 48-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7, filed 6-4-01.

Claims 42 and 46 are under consideration.

In view of Applicant's submission filed on 12-11-02, the outstanding rejections have been withdrawn. However a new ground of rejection has been applied.

### *Information Disclosure Statement*

Reference BU has no translation into English. However in view of the concise summary of Reference BU in the Remarks Section of the Amendment filed 12-11-02, said reference has been considered. Please see the attached copy of the 1449 form.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42 and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The instant claims are drawn to a method of treating Acquired Immunodeficiency Disease (AIDS) comprising administering a combination of an antibody to gamma interferon, ( $\gamma$ IFN), an antibody to alpha interferon ( $\alpha$ IFN), and an antibody to tumor necrosis factor alpha, ( $\text{TNF}\alpha$ ), wherein said antibody is a monoclonal antibody, a polyclonal antibody, and biologically active fragments thereof, or allelic or species variants thereof.

The instant specification discloses in Example 7 that AIDS patients when injected with anti-IFN $\alpha$  antibodies reported an increased sense of wellbeing, energy, appetite and a disappearance of skin rashes. Said example 7 also discloses that in light of the consistently positive effect that has resulted from the combined neutralization of IFN $\alpha$ , IFN $\gamma$  and/or TNF in patients with other autoimmune diseases, similar effects are seen in AIDS patients when treated with the combined antibodies of the present invention. However, said effects appear to be prophetic, especially since said Example does not specify whether the administered anti TNF antibodies are directed against TNF $\alpha$  or TNF $\beta$ .

With regard to a method of treating AIDS, *In re Fisher*, 1666 USPQ 19 24 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. That the area of treating AIDS using the recited combination of antibodies is unpredictable based on Merck Manual of Medical Information's disclosure that AIDS is treated with reverse transcriptase inhibitors and protease inhibitors (see pages 1018-1019), with no mention of treatment comprising administering a combination of an antibody to gamma interferon, ( $\gamma$ IFN), an antibody to alpha interferon ( $\alpha$ IFN), and an antibody to tumor necrosis factor alpha, ( $\text{TNF}\alpha$ ), as instantly recited.

The instant specification discloses on page 34 a successful method of treating Rheumatoid Arthritis (RA) and Ankylosing Spondylitis comprising administering anti-TNF $\alpha$  antibodies, anti-IFN $\alpha$  antibodies and anti IFN $\gamma$  antibodies. The instant specification also discloses that a common mechanism underlies all autoimmune disease (page 40 last paragraph and page 41, lines 10-18). The specification further discloses in Example 7 that in light of the consistently positive effect that has resulted from the combined neutralization of IFN $\alpha$ , IFN $\gamma$  and/or TNF in patients with other autoimmune diseases, similar effects are seen in AIDS patients when treated with the combined antibodies of the present invention. However, the instant specification provides insufficient guidance and direction regarding the extrapolation of said method of treating RA and Ankylosing Spondylitis, to applying said method to the treatment of AIDS. The Examiner notes the lack of a working example demonstrating said prophetic treatment. Further, the Examiner notes that Paul et al teach that the mechanism of autoimmune diseases is diverse and incompletely understood (see Paul, *Fundamental Immunology*, Fourth Edition, 1999, page 1083, column 2, first line of last paragraph). In view of the unpredictability in the art regarding the diverse mechanism and etiology of any autoimmune disease, in particular, AIDS, predicting which autoimmune diseases IE AIDS, can be treated by the method recited in the instant claims (with the exception of treating RA and ankylosing spondylitis) is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly extensive and undue. See *Amgen, Inc. v. Chugai Pharmaceutical Co. Ltd.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991) at 18 USPQ2d 1026-1027 and *Ex parte Forman*, 230 USPQ 546 (BPAI 1986).

With regard to the recitation of the term "biologically active fragment", the specification discloses on page 21, lines 1-4, that said phrase is intended to mean a part of a complete

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molecule which retains all or some of the catalytic or biological activity possessed by the complete molecule, especially activity that allows specific binding of the antibody to an antigenic determinant. However, since no biologically active fragment of an antibody, other than an antigen binding fragment, is disclosed in the instant specification, it would require undue experimentation to predict which biologically active fragments of an antibody, other than an antigen binding fragment, would be effective in the recited method, without further guidance from the instant specification.

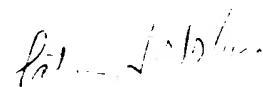
No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.  
Patent Examiner,  
May 29, 2003

  
Patrick J. Nolan, Ph.D.  
Primary Patent Examiner  
Group 1640